DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

939500

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

April 15, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 16

James B. Hickey, Jr.
President and CEO
Pulmonetic Systems, Inc.
17400 Medina Road, Suite 100
Minneapolis, Minnesota 55447-1341

Dear Mr. Hickey:

During an inspection of your establishment located in Minneapolis, MN, on October 11 – December 23, 2002, our investigators determined that your establishment manufactures LTV Series Ventilators which are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), as follows:

1. Procedures were not followed for the identification, documentation, validation or verification, review and approval of design changes before their implementation, which is required by 21 CFR 820.30(i). Specifically, the procedures used to control Engineering Change Orders (ECOs), Document Number 400-002, were not followed. For example, ECO 1574, approved on 12/17/01, does not contain any reference to verification, validation, or rationale for not verifying / validating.

2. Procedures for implementing corrective and preventive actions were not implemented as required by 21 CFR 820.100(a). Specifically, Procedure 100-005, Corrective and Preventive Action, was not invoked in your firm's handling of two quality assurance problems that led to recalls.

3. Appropriate sources of quality data are not adequately analyzed to identify potential and existing causes of nonconforming product and other quality problems. This is required by 21 CFR 820.100(a)(1). For example, your corrective and preventive action (CAPA) system failed to fully assess recurring ~~~~ anomalies in a timely manner.

4. Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements were not implemented as required by 21 CFR 820.50. Specifically, your firm did not have a signed agreement with the contract manufacturer of printed circuit board assemblies as required by your Contract Manufacturing Procedures, 300-022.

5. There was no agreement with a supplier that they notify you of changes in the product or service, which is required by 21 CFR 820.50(b). Specifically, until 10/30/02, there was no written agreement with the contract manufacturer of printed circuit board assemblies that they would notify you of changes.

6. Document control procedures were not implemented as required by 21 CFR 820.40. Specifically, eight (8) out of 21 ECOs reviewed had hand-written changes that were not initialed or dated, or had changes that were made after approval of the ECOs.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We have received your January 8, 2003, response to the FDA-483 issued on December 23, 2002. The corrective actions that you have reported appear to be adequate, but only if you fully implement your established quality system procedures in the operation of your firm. We will conduct a follow-up inspection in the near future to assess your compliance with the Quality System Regulation.

Please update this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to ensure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

For your information, CDRH is concerned with the timeliness of the completion of your recall activities for Class I and significant Class II recalls. Given that these devices are tracked devices, it is reasonable to expect that these activities would be completed in a timely manner. Please provide a copy of your device tracking procedures for review and a summary of any tracking audits that your firm has conducted to confirm the effectiveness of your procedures. Also, please indicate when you expect recalls Z-1047/1050-2, Z-1132/1135-2, and Z-0010/0013-03 will be completed.

Your response should be sent to Compliance Officer Timothy G. Philips at the address indicated on the letterhead. If you have any questions concerning this matter, please contact Mr. Philips at (612) 758-7133.

Sincerely,

Annette Byrne for

W. Charles Becoat
Director
Minneapolis District

TGP/ccl